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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/788,481	ACCOMAZZI ET AL.			
		Examiner	Art Unit			
		Eueng-nan Yeh	2624			
	The MAILING DATE of this communication app	-				
	Period for Reply					
WHICH - Extensic after SIX - If NO pe - Failure t Any repl	RTENED STATUTORY PERIOD FOR REPLY EVER IS LONGER, FROM THE MAILING DAYS OF THE MAILING	ATE OF THIS COMMUNIC, 16(a). In no event, however, may a reprill apply and will expire SIX (6) MONTI cause the application to become ABA	ATION.  bly be timely filed .  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).			
Status			•			
1)□ R	esponsive to communication(s) filed on		•			
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
· ·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Dispositio	n of Claims		·			
4)⊠˙ C	claim(s) <u>1-29</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)□ C	claim(s) is/are allowed.					
	laim(s) <u>1-29</u> is/are rejected.	,				
	claim(s) is/are objected to.					
8)∐ C	claim(s) are subject to restriction and/o	r election requirement.				
Application Papers						
9)⊠ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>26 October 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority un	der 35 U.S.C. § 119	•				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
<ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  Notice of Informal Patent Application						
Paper No(s)/Mail Date Mar 10, 2005; Jun 9, 2004.						

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#### **DETAILED ACTION**

# Specification ...

- 1. The disclosure is objected to because of the following informalities and appropriate corrections are required:
  - ABSTRACT: line 6, "the same structure as said see point". The "see point"
     should be corrected as "seed point".
  - Page 15, lines 11 and 12, "then at block 272". The correct block number is 276.

## Claim Objections - 37 CFR 1.75(a)

2. The following is a quotation of 37 CFR 1.75(a):

The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.

- 3. Claims 9, 14, and 25 are objected to under 37 CFR 1.75(a), as failing to particularly point out and distinctly claim the subject matter which application regards as his invention or discovery:
  - a) Claim 9, line 1, "A method according to claim 7". It is the claim 8 which has said plurality of paths. The "to claim 7" appears to be a typographical error. In light of the corresponding written description of the invention, and for purpose of this examination, the following assumption will be used "A method according to claim \$\neq 8\".

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b) Claim 14, "A method according to claim 12". The "to claim 12" appears to be a typographical error. In light of the corresponding written description of the invention, and for purpose of this examination, the following assumption will be used "A method according to claim 12 13".

c) Claim 25, line 3 "selecting said initial location". There is no existence of the "said initial location" for this independent claim. This appears to be a typographical error. In light of the corresponding written description of the invention, and for purpose of this examination, the following assumption will be used "selecting said an initial location".

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-3, 6-7, 20-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of George, III et al. (US 6,175,655 B1) and Udupa et al. (US 5,812,691).

Regarding claim 1, George discloses a segmentation system comprising: selecting an initial location within the structure to be segmented ("In one embodiment, the method comprises the steps of forming a morphological skeleton of the three-

dimensional data set, selecting a seed data point within the morphological skeleton so as to identify a desired anatomical structure to be displayed or analyzed ..." at column 3, line 43);

assigning to each of the data points a value of connectivity indicative of the confidence that respective ones of the data points are part of the same structure as said initial location, said value of connectivity including a function of the distance of the respective point from said initial location ("...fuzzy connectivity to define additional data points of the desired anatomical structure so as to reconstruct substantially only the desired anatomical structure ..." at column 3, line 48. See also, "Connectivity is a mathematical concept ... by defining a function over a set representing degrees of membership such that membership varies from zero which indicates no membership to one which indicates complete membership" at column 6, line 24. Furthermore, "To define connectivity, this algorithm utilizes a fuzzy generalization of mathematically defined distances between sets as a connectivity criterion. This criterion establishes that if two points or two sets of points are within a specified distance of one another, then they have membership to the same set of points" at column 6, line 35).

George does not explicitly disclose the threshold value for the connectivity and the relationship between selecting data point and threshold value.

Udupa, in the same field of endeavor of image segmentation ("... identifying all fuzzy objects present in image data by segmenting the image ..." at column 1, line 16), teaches the threshold value for the connectivity "... determining the strength of connectedness or "hanging togetherness" of each spatial element in the digital

representation of the scene with other spatial elements in the digital representation of the scene. Those spatial elements having strengths of connectedness with other spatial elements above a predetermined threshold are then clustered into a fuzzy connected component of a fuzzy object in the scene ..." at column 5, line 9. Furthermore, "The volume distribution of the fuzzy connected component may also be calculated by the processing means for different settings of the predetermined threshold. In other words, the volume distribution is different for different thresholds. Preferably, the strength of connectedness of spatial elements in the digital representation of the scene has any of a number of values so that the determination of the strength of connectedness along paths between spatial elements is truly dynamic ..." at column 5, line 20. Thus, the threshold defines the strength of connectedness can affect the number of data volume size represents a segmented feature and vise versa.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to include the segmentation system George made with a robust connectivity threshold and volume distribution as taught by Udupa, in order to effectively "permit extraction of a specified fuzzy object and identification of all fuzzy objects present in image data" at Udupa column 4, line 53.

Regarding claim 2, monitoring variations in said predetermined parameter along a path between said points and utilizing a function employing variations in said parameter as an indicator of said value of connectivity ("To define connectivity, this algorithm utilizes a fuzzy generalization of mathematically defined distances between

sets as a connectivity criterion ..." at George column 6, line 35. See also Udupa column 8, lines 15 to 60).

Regarding claim 3, the length of said path is combined with said function employing variations of said parameter to obtain said value of connectivity (discussed in claim 1, "...fuzzy connectivity to define additional data points of the desired anatomical structure so as to reconstruct substantially only the desired anatomical structure ..." at column 3, line 48. See also, "Connectivity is a mathematical concept ... by defining a function over a set representing degrees of membership such that membership varies from zero which indicates no membership to one which indicates complete membership" at column 6, line 24. Furthermore, "To define connectivity, this algorithm utilizes a fuzzy generalization of mathematically defined distances between sets as a connectivity criterion. This criterion establishes that if two points or two sets of points are within a specified distance of one another, then they have membership to the same set of points" at column 6, line 35).

Regarding claim 6, threshold value is adjustable to vary the data points selected for display (discussed in claim 1, "The volume distribution of the fuzzy connected component may also be calculated by the processing means for different settings of the predetermined threshold. In other words, the volume distribution is different for different thresholds. Preferably, the strength of connectedness of spatial elements in the digital representation of the scene has any of a number of values so that the determination of

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the strength of connectedness along paths between spatial elements is truly dynamic ..." at Udupa column 5, line 20. Thus, the threshold defines the strength of connectedness can affect the number of data volume size represents a segmented feature and vise versa).

Regarding claim 7, wherein said function employing variations in said parameter is an indication of the maximum variation in said parameter (discussed in Udupa column 8, lines 15 to 60. See also equation 6 at Udupa column 8, line 56).

Regarding claims 20 and 21 (as depicted in Udupa figure 6, numeral 230 the initial location for the segmentation process is selected from pixels with particular feature to be segmented such as white matter ("WM"), gray matter ("GM"), and ventricles ("CT") etc.).

Regarding claim 22, said initial location is selected from examination of a set of data points to identify a characteristic indicative of a particular feature (discussed in claim 21, initial location is selected from examination of a set of data points to identify a characteristic indicative of a particular feature).

Regarding claim 23, an imaging apparatus comprising:

a data store having a set of spatially related data points representing variations in a

predetermined parameter (as depicted in Udupa figure 5, numeral 130 data are stored

in a memory 130. "image data representing T2 and proton density (PD) values are obtained from MR scanner 100 in accordance with a predetermined protocol" at column . 21, line 65);

a comparator to compare a value of said predetermined parameter at said point with that of an initial location and distance of said point from said initial location and establish a value of connectivity indicative of the confidence that respective ones of said data points are part of the same structure (as depicted in Udupa figure 5, numeral 170 the processor is the comparator which assigns each data point a distance related connectivity indicative of the confidence as discussed in claim 1); a selector to select respective points that meet an established threshold (as depicted in Udupa figure 6, numeral 300 compute volume which will select data that meet an established threshold as discussed in claim 1).

Regarding claim 25, a method of segmenting an image comprising the steps: selecting said an initial location from an examination of a data set of said structure to identify particular characteristics of said structure (discussed in claim 1, "In one embodiment, the method comprises the steps of forming a morphological skeleton of the three-dimensional data set, selecting a seed data point within the morphological skeleton so as to identify a desired anatomical structure to be displayed or analyzed ..." at George column 3, line 43).

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Regarding claim 26, wherein said data set is said set of data points (discussed in claim 25, said data set is said set of data points of morphological skeleton of the three-dimensional data set).

Regarding claim 27, said data set is obtained from a set of data points other than those being segmented (as depicted in Udupa figure 6, numeral 230 the initial location for the segmentation process is selected from pixels with particular feature to be segmented such as white matter ("WM"), gray matter ("GM"), and ventricles ("CT") etc. Thus, said data set is obtained from a set of data points other than those being segmented).

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of George and Udupa as applied to claims discussed above, and further in view of Zhang et al. (US 2003/0144598 A1).

Regarding claim 4, the George and Udupa combination discloses a segmenting system with distance related connectivity function. The George and Udupa combination does not explicitly teach weighting factor to vary the effect of distance on the connectivity.

Zhang, in the field of endeavor of "automatic nodule detection" in paragraph 22, line 2, teaches a weighting factor can be used to apply to distance to affect the confidence level as depicted in figure 9: "... A distance confidence function 916, based on the distance between the nearest vessel and the airway candidate, is scaled by

weighting factor beta at multiplier 918 ... A decision block 924 receives the overall confidence level and determines whether it is greater than or equal to a threshold value  $T_{conf}$ ... If the overall confidence is not less than  $T_{conf}$ , function block 926 determines that the candidate is located on an airway. If the overall confidence is less than  $T_{conf}$ , function block 928 determines that the candidate is not located on an airway" in paragraph 44, line 8. Without departing from the essence of Zhang's methodology, a weighting factor can be used to vary the effect of distance on the value of connectivity.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the segmenting system of the George and Udupa combination, to include the distance weighting factor as taught by Zhang, to enhance the confidence level thus "improve the overall diagnostic accuracy" in paragraph 52, line 5.

Regarding claim 5, weighting factor is variable (discussed in claim 4, as depicted in Zhang figure 9, numeral 918 variable beta is the weighting factor).

7. Claims 8-9 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of George and Udupa as applied to claim1 discussed above, and further in view of Dellepiane et al. (IEEE, Vol. 5, No. 3 March 1996, pp. 429-446).

Regarding claim 8, the George and Udupa combination discloses a segmenting system with distance related function for each data point to determine the connectivity. The George and Udupa combination does not explicitly teach the multivalue characteristics of segmentation results.

Dellepiane, in the same field of endeavor of image segmentation ("multivalue characteristics of segmentation" at page 429, right column, line 30), teaches a multivalue labeling with each pixel a value ranging from zero to one. "On the basis of this result, a segmented image can be interpreted as a topological map from which one can derive a set of object areas or contours. The highest membership values correspond to points that are most likely to belong to a searched object" at page 431, left column, bottom paragraph. The plurality of paths are depicted in figure 1.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the segmenting system of the George and Udupa combination, to include multivalue characteristics of segmentation as taught by Dellepiane, which proved by the results obtained on real images to be "good quality of results and the robustness and the speed of the method" at page 429, right column, line 43.

Regarding claim 9, plurality of paths is limited by application of a volume size value (discussed in claim 1, the threshold and the number of data volume size are mutually related which limits the plurality of paths).

Regarding claim 24, a path selector to select a plurality of paths between said initial location and each of said respective points, said comparator selecting a maximum value of connectivity (as depicted in Udupa figure 5, numeral 170 processor is the path selector will select a plurality of paths as discussed in claim 8. See also Dellepiane equation (3.3) for the maximum connectedness).

8. Claims 10-19 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of George and Udupa as applied to claims discussed above, and further in view of Turek et al. (US 6,754,376 B1).

Regarding claim 10, the George and Udupa combination discloses a segmenting system with distance related connectivity function. The George and Udupa combination does not explicitly teach value mapping.

Turek, in the same field of endeavor of image segmentation ("segmenting threedimensional (3D) structures from a series of cardiac images" at column 1, line 7, teaches an automatic segmentation method "The vessel segmentation process automatically evaluates the image data in accordance with predetermined classification values to extract desired portions of the data to keep for the vessel visualization and to discard portions not desired. These classification values include pixel intensity or CT number of the pixels, pixel location relative to the seed point, the size of similar pixel groupings, and pixel connectivity in both two and three dimensions" at column 2, line 49. As depicted in figure 2 "... At 201, the input volume data is evaluated against a threshold in a known manner to produce a binary mask of pixels that are in the value range of interest, and those that are outside that range ... In this embodiment, the classification value or threshold is a measure of pixel intensity often referred to as CT number and measured in Hounsfield units ... as a result of thresholding at 201, pixels are turned "on" if they are part of a certain range of CT numbers and are turned "off" if they are not a part of the range of CT numbers. The binary mask resulting from applying

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a threshold to the input CT values is the input to the two parts of the segmentation process ..." at column 3, line 38. Thus, data are evaluated on the basis of threshold which as a mapped table value referred to as CT number in Hounsfield units.

It would have been obvious at the time the invention was made to one of ordinary skill in the art to modify the segmentation system of the George and Udupa combination, to include the value mapping as taught by Turek, such that the created mask can be used by the "automatic segmentation method" at column 3, line 10.

Regarding claim 11, values of said predetermined parameter are compared to a predefined range of values and those outside said range modified (discussed in claim 10, pixels are turned "off" if they are not a part of the range of CT numbers).

Regarding claim 12, said values are modified by reducing said values to zero (discussed in claim 11, "off" means value zero).

Regarding claim 13, an area of said image is selected and values of said predetermined parameter in said area are modified (discussed in claim 10, the methodology applies to volume data too).

Regarding claim 14, values are modified by reducing said values to zero (discussed in claim 10, "off" means value zero).

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Regarding claim 15, values of said predetermined characteristic are exceeding said threshold are changed to a common value (discussed in claim 10, pixels are turned "on"/"off" based on the threshold range of CT numbers).

Regarding claim 16, values of said predetermined parameter are compared to say initial location and those within predefined limits of that of said initial location are selected for further processing (discussed in claim 10. See also "All the "on" pixels that are connected to the seed point specified by the user are kept ..." at Turek column 3, line 66).

Regarding claim 17, the number of the selected data points is compared to an anticipated value (discussed in claim 10, "The vessel segmentation process automatically evaluates the image data in accordance with predetermined classification values to extract desired portions of the data to keep for the vessel visualization and to discard portions not desired. These classification values include pixel intensity or CT number of the pixels ... " at Turek column 2, line 49. Thus, in order to extract desired portions of data, the segmentation process will evaluate number of selected image data points with predetermined classification values such as anticipated CT number of pixels).

Regarding claim 18, said threshold is adjusted to bring said number of selected data points into conformity with said anticipated value (discussed in claim 1, "The

volume distribution of the fuzzy connected component may also be calculated by the processing means for different settings of the predetermined threshold. In other words, the volume distribution is different for different thresholds. Preferably, the strength of connectedness of spatial elements in the digital representation of the scene has any of a number of values so that the determination of the strength of connectedness along paths between spatial elements is truly dynamic ..." at Udupa column 5, line 20. Thus, the threshold defines the strength of connectedness can affect the number of data volume size represents a segmented feature and vise versa. Therefore, the threshold can be adjusted to bring said number of selected data points into conformity with said anticipated value).

Regarding claim 19, wherein said set of selected data points represents a volume of a structure (discussed in claim 10 for three dimensional image segmentation).

Regarding claim 28, a method of segmenting an image comprising the step of: establishing a first number of data points expected to represent a segmented feature of said image (discussed in claim 10, "The vessel segmentation process automatically evaluates the image data in accordance with predetermined classification values to extract desired portions of the data to keep for the vessel visualization and to discard portions not desired. These classification values include pixel intensity or CT number of the pixels ... " at Turek column 2, line 49. Thus, this predetermined classification value

of CT number of pixels is the first number of data points expected to represent a segmented feature of said image);

establishing a threshold value of a characteristic of said data set, determining a second number of data points meeting said threshold (discussed in claim 1, "The volume distribution of the fuzzy connected component may also be calculated by the processing means for different settings of the predetermined threshold. In other words, the volume distribution is different for different thresholds. Preferably, the strength of connectedness of spatial elements in the digital representation of the scene has any of a number of values so that the determination of the strength of connectedness along paths between spatial elements is truly dynamic ..." at Udupa column 5, line 20. Thus, the threshold defines the strength of connectedness can determine the number of data points meeting the said threshold as the second number of data points); comparing said first and second number of data points (discussed in the first part of claim 8 that segmentation process automatically evaluates the image data i.e. comparing said first and second number of data points).

Regarding claim 29, including the step of adjusting said threshold to correlate said first and second numbers (discussed in claims 17 and 28, in order to extract desired portions of data, the segmentation process will adjust said threshold to correlate said first and second numbers of data points).

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### Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Hartley et al. (US 5,903,664): segmentation with seed on ROI with 3-D connectivity.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eueng-nan Yeh whose telephone number is 571-270-1586. The examiner can normally be reached on Monday-Friday 8AM-4:30PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2.4.

Eueng-nan Yeh Assistant Patent Examiner 2624

VIKKRAM BALI PRIMARY EXAMINER